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To: NOSB Materials and Handling Committees
June 13, 2005

Re: Draft position from Materials Committee on the Definition of Synthetic.

Dear NOSB members,

We have reviewed the proposed clarification provided by the Materials Committee for the definition of synthetic, which is a very useful and thorough document. We believe it provides a good basis for guidance of the Board's work in reviewing substances for the National List. The determination of synthetic or nonsynthetic status is a critical, yet difficult task for the Board, and this guidance should provide a sound basis for decision-making. We have suggested some changes and additional suggestions, attached and provided in a highlighted revision mode format. Comments are also provided as support for the proposed changes.

As guidance, we believe that this needed clarification can be accomplished without regulatory changes. The definition of synthetic in OFPA is well established, and this clarification should help amplify the meaning for use by the Board as well as for petitioners and producers.

We write as organic consumers and as persons experienced in materials review and organic certification. Dr. Walker is a research chemist who serves on the OMRI advisory council. Thank you for the opportunity to provide these comments.

Sincerely,

Emily Brown Rosen

Alfred T. Walker, PhD.
217 Street Rd.
Oxford, PA 19363

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DRAFT 2
The Materials Process
Clarification of the definition of Synthetic as it is applied to Substances Petitioned for Addition or Prohibition to the National List(s)
Prepared by Rose Koenig, Materials Chairperson
Voted on by Committee as a Discussion Document 2/7/05

Justification: This document is a draft for guidance purposes with the goal of clarifying the definition of synthetic as it pertains to determination for substances petitioned for addition or prohibition to the National List(s).

The NOSB uses the definition of synthetic as:

> A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes. (OFPA 2103 (21); 7 CFR 205.2).

Any substance other than those naturally occurring in a plant, animal or mineral is considered synthetic if it is formulated or manufactured by a chemical process.

I. Recommendation for guidance,

Extraction[1] shall be understood to mean:

Substances removed from naturally occurring plants, animals, or mineral sources can be extracted in any manner and with any substance, material, physical process (i.e. centrifugation, heating, chemical solvents, bases and acids) as long as the extraction process does not chemically change the substance that is being extracted. As long as a chemical reaction does not occur, the substances used in crop production that are removed from a naturally occurring plant, animal or mineral source are nonsynthetic, provided any synthetic substance used in the extraction process do not remain in the final product.

In the case of processing or livestock substances, any extraction from a plant, animal or mineral source must be made in a manner that does not result in a chemical reaction, and any substances used must be reviewed for this purpose.

> ***Comment*** A less stringent policy on extraction for crop inputs that will not enter the food chain directly is reasonable: e.g. extraction of botanicals like pyrethrum using alcohol and other solvents. However, it is not appropriate that extraction of food ingredients are permitted to use synthetics without review, or this policy

[1] Extraction (NOSB, 1995; Austin, Texas); The concentration, separation and removal of a substance from a plant, animal microbiological or mineral source. Materials used in plant crop and animal production may be extracted in any way that does not result in synthetic reaction as defined by 2103(21). The products of any other methods of extraction shall be considered on a case by case basis and reviewed for compatibility under OFPA Sec. 2119 (m) (1-7).

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would allow clearly prohibited actions when applied to processing: e.g. hexane extraction of oil. Likewise, substances that end up in livestock feed or medicine that are considered natural should also meet a strict standard. This is consistent with original NOSB language in footnote.

Formulation or manufacturing shall be understood to mean:
Once a substance is extracted, if it then undergoes a chemical reaction as it is processed, formulated or manufactured to produce agricultural or handling inputs, it then would be considered a synthetic and would have to be petitioned for inclusion on the National List.

Chemical reaction (chemical change) shall be understood to mean:
A chemical reaction has occurred when one or more atoms are removed or added to a molecule. Examples of reactions include: 1) Addition or combination reaction: Two substances combine to form one: $2Na+Cl_2$----2NaCl; 2) Decomposition reactions: One compound breaks into two or more compounds or elements. $CaCO_3$-----$CaO + CO_2$; 3) Displacement reactions: Substances exchange parts. Two examples are hydrolysis (a hydroxyl ion from water is added to a substance and a hydrogen ion from water is added to a second molecule) and acid-base reactions (proton donation or acceptance) and 4) Protein configuration changes as a result of a physical association of a added substance other than that of the native protein.

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"**Substance**" includes compounds and elements. Any synthetic substance for use in crops and livestock, and any nonorganic substance for use in processing with a distinct identity (separate Chemical Abstract Society number, INS number, or FDA or other agency standard of identity) must be separately listed in the National List for use in organic production.

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"Substances created by naturally-occurring biological processes" shall be understood to mean:
Chemical changes that occur in living cells or due to the action of products of living organisms, such as enzymes. For example, lactic acid is a non-synthetic substance that is the result of lactose (milk sugar) being fermented by the bacterium *Lactobacillus*. Organisms altered or created by genetic engineering ("excluded methods") are considered synthetic, along with their products.

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Comment: The NOSB definition limits biological processes to living cells, while another proposal has suggested that biological processes should also be described changes that occur to *molecules* as a result of the components of living organisms. Enzymes are used in many industrial processes, both with living microbes in fermenters and without microbes. Many synthetic enzymes are also available and are getting cheaper all the time (see an Aldrich catalog). Synthetic enzymes can be added to living organisms (sucrose enhancing enzymes added to tomato tissue cultures, or stress tolerance enzymes added to nematodes, for example). The NOSB definition may not prevent these types of additions, as they can be done by traditional tissue culture. The suggested language is provided to clarify that substances created by biological processes are derived from living cells or their products, and to remind producers that natural organisms do not include genetically modified forms or products of these forms.

Additional definitions **Processing**: "Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydration/, evaporation, freezing, chilling, crystallization, pressing or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

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Comment: A change to the definition of processing to add evaporation, crystallization and pressing adds a number of mechanical /physical processes that do not involve chemical reactions. These additions could be proposed as guidance. Combustion and clarification have also been proposed, but do add elements of chemical change that need to be reviewed on a case-by-case basis.

Additional comment on definition of Nonsynthetic

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Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act. [NOP.]

Comment:

While the definition of nonsynthetic that is found in the regulation is non-specific, it is adequate when combined with a NOSB clarification of the synthetic definition. Creation of a new definition for nonsynthetic might cause conflict in reviewing substances to each definition separately.

The suggestion by some commenters that the nonsynthetic determination should be made by evidence of changes in covalent bonding is incomplete. A covalent bond is defined as an equal sharing of valence electrons by several atoms. However, ionic bonding is an equally important form. Metallic or van der Waals bonds are also significant. According to a standard text in inorganic chemistry, an covalent bond occurs "when electrons are equally shared by the participating nuclei" and an ionic bond is "the bonding in molecules in which there is an almost complete electron transfer" from the atom with lower electronegativity to the atom with higher electronegativity (Gray, H. B. 1965, Electrons and Chemical Bonding, Benjamin, NY. 223 p.). In ionic bonding the almost complete electron transfer induces opposite electrical charges on the two atoms. The bond is formed by electrical attraction of the opposite charges, not a sharing of electrons. Covalent bonds are therefore, directional, while ionic bonds are not.

The problem with distinguishing synthetic and nonsynthetic agricultural ingredient based on breaking covalent bonds is that a purely covalent bond rarely, if ever exists. Both covalent and ionic bonds are end states in models made to describe the behavior of chemical bonding in real materials. All four types of bonds have similar definitions in the two main models of chemical bonding; Valence bond and Molecular Orbital Theory. Compounds like silicon or germanium oxide are highly covalent and alkali chlorides like NaCl are almost

purely ionic. Most compounds fall in between, however, and have both covalent and ionic components to their bonds. Some show different types of bonding under different physical conditions. Graphite is a van der Waals solid at low pressure and a highly covalent solid, diamond, at high pressure.

As the NOSB draft notes, many chemical reactions occur without breaking covalent bonds, included reactions between soluble salts, acid base reactions, or hydrolysis.

If two natural soluble salts AX2 and BY are dissolved in water to yield AY2 as the first crystal to precipitate during evaporation, the covalent bond theory would call AY2 nonsynthetic. One can change the compounds that crystallize from a mixture of natural salts by adding weak acids (citric) or bases, changing the temperature or pressure, or by bubbling oxygen through the solution. Clearly these different compounds are synthetically created, yet the proposed change in definition would allow them as natural.

Conclusion

The proposed NOSB clarification of definitions regarding chemical reaction is useful for determining what substances are synthetic, and should be the basis for determination of synthetic status. Further attention to the definition of "extraction" and "substance" will also facilitate the determination. When reviewing processing substances, the NOSB must review the steps of production and determine if a chemical change occurred in manufacture of the substance. This may include whether the substance was extracted from a natural source in an acceptable manner. This should not be confused with possible further chemical changes that may occur in food product formulation due to use of approved cooking or processing techniques.

The background information provided in Section II is excellent, and should be retained for the Board Policy Manual as well as for public information.